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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,702	07/02/2003	Luiz Belardinelli	00-078-D	7957

7590 09/16/2004

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,702

Applicant(s)

BELARDINELLI ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8-9-2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

1. Claims 1-14 are pending in this application.
2. The examiner acknowledges receipt of an IDS dated August 9, 2004 with only the first sheet. It is noted that the form indicates "Sheet 1 of 2". Applicants should resubmit ---Sheet 2 of 2--- if previously submitted.
3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 ends with the phrase "full agonist;" and is therefor not a complete sentence. It is suggested that "full agonist;" be changed to ---full agonist.--- if this is a typographical error.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a correlation step or claim limitation relating how "selecting compounds that have a lower intrinsic efficacy than said full agonist" actually identifies "selective partial A_{2A} adenosine receptor agonists".

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, and 6-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pierce et al (WO 93/25677).

Pierce et al disclose a method of screening a molecule for selective partial A_{2A} adenosine agonist activity, comprising contacting the molecule with the human A_{2A} adenosine receptor in a cell. Pierce et al disclose the receptors have homology to cDNA's encoding A_{2A} adenosine receptors. Also, Pierce et al disclose using the A_{2A} adenosine receptors for homology screening. In addition, Pierce et al discloses that Figure 4B shows competition binding curves showing the displacement of CGS-21680 by different adenosine agonists in mammalian HEK 293 cells expressing the human A_{2A} adenosine receptor. See pages 1-2, lines 1-35; page 3, lines 26-31 and page 4

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lines 1-18 and lines 7-35. Pierce et al further describe a method for producing a human A2A adenosine receptor comprising culturing a cell transformed with the DNA molecule encoding the human A2A. See pages 1-11 and especially note page 3, lines 26-31 and page 11, lines 18-23 and lines 30-34. Pierce et al disclose the receptors may be of clinical and commercial interest. See page 4, lines 1-5. With respect to the cell lines described in the instant claims, Pierce et al disclose the use of Chinese Hamster Ovary (CHO K1) or Human Embryonic Kidney (HEK 293) mammalian cell lines. See page 9, lines 26-35 and page 10, lines 1-25. Also, Pierce et al describe the effects of CGS21680 on A2A receptor activity. Note page 4, lines 27-35, and page 5, lines 1-7. Hence, Pierce et al disclose the method claimed except for specifically describing "...measuring the intrinsic efficacy of a full agonist in said cell line; and c. selecting those compounds that have a lower intrinsic efficacy than said full agonist".

However, Pierce et al disclose a method of screening a molecule for A2A agonist activity in a cell line which encompasses screening A2A adenosine agonist receptors for homology and Pierce et al disclose competitive binding method steps the include A2A adenosine agonist receptors. Thus, Pierce et al address the limitations in steps "b. measuring the intrinsic efficacy of a full agonist in said cell line; and c. selecting those compounds that have a lower intrinsic efficacy than said full agonist" as claimed in the present invention. It is noted that the Pierce et al disclosure of a method for screening a molecule for A2A agonist activity comprises measuring full agonist and/or partial or lower agonist A2A receptor activity. Pierce et al disclose all the claim limitations except for the inherent properties evaluated by "measuring the intrinsic efficacy of a full agonist

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in said cell line; and c. selecting those compounds that have a lower intrinsic efficacy than said full agonist" which anticipates or renders obvious the invention as claimed.

The burden of proof is on applicants to show patentably distinct differences between the Pierce et al disclosure and the method claimed in the present invention.

5. The Belardinelli et al document (US 20020012946 A1); Linden et al references (US 6,322,771 B1 and 6,448,236 B1) and Zablocki et al references (US 6,552,023 B2 and 6,677,336 B2) have been cited to further show the stat of this art.

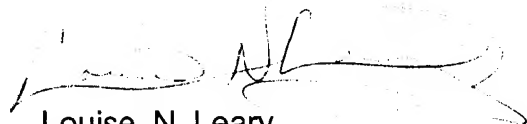
6. Claims 5 and 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571)272-0966. The examiner can normally be reached on Monday to Friday from 9:30 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louise N. Leary
Primary Examiner
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September 4, 2004